



COVID-19 vaccine considerations for group health plans

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Now that COVID-19 vaccines have started shipping across the United States, group health plan sponsors must understand the coverage requirements for the vaccines. Coronavirus relief enacted in March requires group health plans and issuers to cover COVID-19 vaccines and other preventive services without cost sharing. An [interim final rule](#) issued in November provides guidelines for the COVID-19 preventive-services coverage requirement. The rule took effect immediately and sunsets at the end of the COVID-19 public health emergency. This GRIST reviews the provisions of the rule affecting group health plans' coverage of COVID-19 preventive services and other important considerations for employers.

Overview of COVID-19 vaccine coverage mandate

Section [6001](#) of the Families First Coronavirus Response Act (FFCRA) (Pub. L. No. 116-127), as amended and expanded by Sections [3201](#) and [3202](#) of the Coronavirus Aid, Relief and Economic Security (CARES) Act (Pub. L. No. 116-136), requires group health plans to cover COVID-19 testing and related services at no cost to plan participants during the [public health emergency](#), as determined by the Health and Human Services (HHS) secretary. Triagency FAQs issued in April and June (Parts [42](#) and [43](#)) explain the testing coverage provisions for group health plans and issuers.

The CARES Act ([Section 3203](#)) builds upon the testing mandate and requires coverage of COVID-19 vaccines (and other COVID-19 preventive items and services) without cost sharing. Unlike the testing mandate, the vaccine coverage mandate has no expiration date. An [interim final rule](#) addresses the

COVID-19 preventive-services coverage requirement, among other topics. The rule took effect Nov. 2, but the agencies will accept comments on certain issues until Jan. 4, 2021.

Expedited coverage of COVID-19 preventive services

The CARES Act requires nongrandfathered group health plans and issuers to cover COVID-19 vaccines and other preventive services without cost sharing on an expedited time frame. COVID-19 preventive services must be covered without cost sharing beginning just 15 business days after a recommendation from Centers for Disease Control and Prevention (CDC)'s Advisory Committee on Immunization Practices (ACIP) or an "A" or "B" recommendation from US Preventive Services Task Force (USPSTF). In contrast, the Affordable Care Act (ACA) requires coverage of other new preventive services without cost sharing by the first plan year starting on or after one year from the end of the month when USPSTF or ACIP made the recommendation.

Interim final rule expands cost and coverage requirements

The interim final rule provides guidance to implement the CARES Act's coverage mandate for COVID-19 preventive services. The coverage requirements go beyond what some plan sponsors might have expected. Although the interim final rule sunsets at the end of the public health emergency, the CARES Act's coverage requirement has no expiration date.

No-cost-sharing requirement extends to out-of-network services

The CARES Act requires group health plans and issuers to cover "any qualifying coronavirus preventive service" without cost sharing (such as a copayment, coinsurance or a deductible). The interim final rule extends this requirement to qualifying coronavirus preventive services received from *out-of-network* — in addition to in-network — providers during the public health emergency.

The requirement to cover out-of-network COVID-19 preventive services without cost sharing during the public health emergency may come as a surprise to some. In contrast, 2015 [ACA preventive-services regulations](#) require coverage of other preventive items and services without cost sharing only when received from in-network providers, assuming enough are available to provide the item or service. As long as an in-network provider is available, a plan can deny coverage from an out-of-network provider or impose cost sharing on participant who receives preventive services from an out-of-network provider.

In the preamble to the interim final rule, the agencies explain that the limited initial supply of COVID-19 vaccines will limit the number of in-network providers with access to vaccine. As a result, regulators believe requiring COVID-19 preventive-services coverage without cost sharing from any provider during the public health emergency is necessary to ensure full access and widespread use of COVID-19 vaccines and preventive services.

The COVID-19 public health emergency is currently set to expire on Jan. 20, 2021, although the HHS secretary can extend the period for another 90 days. Once the public health emergency expires, the COVID-19 preventive-services coverage mandate will continue to apply, but only on an in-network basis. The agencies invite comments on how long provider networks for delivering COVID-19 vaccines may remain inadequate. Regulators could extend the requirement to cover out-of-network COVID-19 preventive services without cost sharing beyond the public health emergency, if warranted by limited in-network access.

Reimbursements for out-of-network providers must be reasonable. The interim final rule imposes “reasonable” minimum payment standards for out-of-network providers. A reasonable reimbursement is determined in comparison to the prevailing market rates for the particular qualifying coronavirus preventive service. The preamble to the rule suggests that a reimbursement equal to what Medicare pays providers for the item or service would be reasonable. The Centers for Medicare & Medicare Services (CMS) [toolkit for providers](#) indicates that Medicare will pay \$28.39 to administer single-dose vaccines. For COVID-19 vaccines requiring multiple doses, Medicare will pay \$16.94 for administration of the initial dose(s) and \$28.39 for the final dose. These rates will be geographically adjusted.

In the preamble to the interim final rule, the agencies explain that “unreasonably low” reimbursement rates for out-of-network providers would “severely limit” the number of providers willing to administer COVID-19 preventive services. Requiring reasonable reimbursements for out-of-network providers ensures plan participants have meaningful access to those services. In addition, providers participating in the CDC’s [COVID-19 vaccination program](#) have to administer the vaccine regardless of an individual’s health coverage or ability to pay and may not balance bill the recipient.

The agencies invite comments until Jan. 4, 2021, on the minimum payment standard, including whether other examples of reasonable reimbursement rates for out-of-network providers would be useful.

Qualifying coronavirus preventive service defined

The interim final rule clarifies a technical difference between a “qualifying coronavirus preventive service” as defined in the CARES Act and the typical immunizations covered by the ACA’s preventive-services mandate. The rule summarizes the CARES Act definition (Section 3203(b)(1)) of a qualifying coronavirus preventive service as:

an item, service, or immunization that is intended to prevent or mitigate COVID-19 and that is (A) an evidence-based item or service that has in effect a rating of “A” or “B” in the current recommendations of the USPSTF; or (B) an immunization that has in effect a recommendation from ACIP with respect to the individual involved.

This definition is consistent with the ACA’s statutory language on preventive services. However, the 2015 ACA preventive-services regulations limit coverage without cost sharing to only immunizations that

ACIP recommends for “routine use.” In the interim final rule for COVID-19 preventive-services coverage, regulators note that COVID-19 immunizations might not be recommended for routine preventive services but rather for urgent use, given the unique circumstances presented by the COVID-19 public health emergency. Accordingly, COVID-19 immunizations meeting the statutory definition must be covered without cost sharing, even if they are not listed for routine use by the CDC.

Vaccine may be free, but plans shoulder the cost of administration

Nongrandfathered group health plans must cover the cost of COVID-19 vaccine administration, even if the cost of the vaccine itself is paid by a third party like the federal government. The interim final rule clarifies that “items and services that are integral to the furnishing of the recommended preventive service” must be covered without cost sharing, *even if billed separately*. This means plans must cover both the vaccine and its administration without cost sharing, regardless of how the administration is billed and the number of doses required for full vaccination.

This clarification applies to all recommended preventive services, not just COVID-19. For example, nongrandfathered plans must cover without cost sharing both the specimen collection and the laboratory work necessary for diabetes screening, regardless of how they are billed.

Limitations on cost sharing for office visits. The regulators describe the clarification as consistent with examples in the 2015 ACA preventive-services regulations and earlier subregulatory guidance. That guidance prohibits cost sharing for an office visit where a patient receives a preventive service, but only if the visit is not billed separately and its primary purpose is to deliver the preventive service. If the office visit is billed separately, or is not billed separately and the primary purpose of the visit was not to obtain preventive services, then cost sharing for the visit (but not the preventive service) can apply.

In the case of COVID-19 vaccines, since administration is integral to the immunization, cost sharing is prohibited for administration. Cost sharing for an office visit made for the primary purpose of obtaining the immunization is prohibited if the visit and immunization are *not* billed separately (or are not tracked as separate encounters). This presumably means that if the office visit is billed separately from the vaccine and its administration, or if the primary purpose of the visit was not to receive the immunization, cost sharing can apply for the office visit.

Employer considerations

The COVID-19 vaccines and the CARES Act coverage requirement present a number of employer considerations, including direct access to the vaccines for an employer’s workforce, cost implications of covering the vaccine and its administration, and potential safety protocols to require the vaccine for returning to the workplace. Each of these issues should be carefully reviewed with health insurance issuers or third-party administrators, employee benefit advisors, and legal counsel.

Covering the vaccine

The CARES Act coverage requirement is straightforward: Health insurance issuers and nongrandfathered group health plans — whether insured or self-funded — must cover *any* qualifying coronavirus preventive services without cost sharing. This includes a carve-out pharmacy plan provided alongside a major medical plan. Whether delivered in network, out of network, or at a physician's office, a pop-up clinic, a pharmacy or some other nontraditional setting, approved COVID-19 vaccines must be covered without cost sharing.

Timing is critical. Although plans technically have 15 business days after an ACIP or USPSTF recommendation to begin covering a COVID-19 vaccine without cost sharing, CMS urges all plans and issuers to prepare to cover these vaccines immediately upon recommendation to maximize rapid public take-up. On Dec. 11, the [Food and Drug Administration](#) (FDA) [authorized](#) the Pfizer-BioNTech COVID-19 vaccine for emergency use in individuals ages 16 or older, allowing distribution to begin in the United States. On Dec. 12, ACIP issued an [interim recommendation](#) for the Pfizer vaccine, triggering the CARES Act coverage requirement for group health plans and issuers. On Dec. 18, the FDA [authorized](#) the Moderna COVID-19 vaccine for emergency use in individuals ages 18 or older, and ACIP [recommended](#) the vaccine on Dec. 19. Two other companies backed by [Operation Warp Speed](#) — AstraZeneca-Oxford and Johnson & Johnson — expect to seek approval of their vaccines in January or February 2021.

Coverage through on-site clinics, EAPs and grandfathered plans. Some employers may be considering offering or covering the vaccine through an on-site clinic or an employee assistance program (EAP). On-site clinics and most EAPs are excepted benefits exempt from the preventive-services coverage mandate. Nevertheless, if a COVID-19 vaccine is available through these alternatives, a [CMS toolkit](#) encourages coverage without cost sharing for all enrollees. CMS likewise encourages grandfathered health plans exempt from the mandate to provide no-cost coverage for the vaccines.

Review whether a stand-alone COVID-19 vaccine program would be an ERISA health plan. Some employers may be interested in offering a stand-alone COVID-19 vaccine program in the workplace, similar to a routine employer-provided flu shot clinic. Before doing so, employers should consult with counsel to determine whether the program would be considered an ERISA group health plan. Unlike a typical flu shot, some COVID-19 vaccines require multiple shots over a number of weeks. The organization and operation of such a clinic could be considered an ongoing administrative scheme that rises to the level of an ERISA plan that provides continuing medical care, treatment and follow-up.

ERISA comes with many compliance requirements — for example, reporting, disclosure and fiduciary obligations. However, a vaccine program's status as an ERISA health plan could also serve to protect the employer from potential medical tort claims arising from a new vaccine (and its administration) that might have serious side effects for some people.

Accessing the vaccine

Some employers are looking for ways to access and administer vaccines directly to employees. This is likely impossible for most employers, and even the few employers well positioned to transport and administer the vaccines may find the task difficult to coordinate. The vaccines, purchased by the federal government, will be distributed to the states and localities according to each jurisdiction's prioritization plan. The states and localities will then distribute the vaccines to facilities for administration to prioritized groups. Private employers will not be able to purchase vaccines directly from vendors or manufacturers. Employers can review the relevant [state prioritization protocol](#) or contact a state's public health authority to see where their employees might fit into the distribution plan.

ACIP [recommends](#) a phased approach to the distribution of initial supplies of the COVID-19 vaccines. Phase 1 includes multiple subparts:

- **[Phase 1a: High-risk healthcare workers and residents of long-term care facilities.](#)** This group includes health workers involved in direct patient care (for example, hospital, nursing home and home care staff), including transportation, environmental service, and other healthcare facility service workers at risk of exposure to bodily fluids or aerosols.
- **[Phase 1b: People ages 75 or older and frontline essential workers.](#)** Frontline essential workers include those in sectors essential to the functioning of society who are at substantially higher risk of exposure to COVID-19. This group includes first responders, educators, and workers in public transport, manufacturing, food and agriculture, grocery stores, the US Postal Service, and correctional facilities.
- **[Phase 1c: Other essential workers, people ages 65 to 74, and people ages 16 to 64 with a high-risk medical condition.](#)** This group includes workers in transportation, food service, finance, housing, communication, energy, media, legal, public safety and water management. For individuals with medical conditions, the CDC currently lists the following as increasing the risk of severe COVID-19 disease: cancer, chronic kidney disease, chronic obstructive pulmonary disease, immunocompromised state from a solid organ transplant, obesity, serious heart conditions, sickle cell disease and type 2 diabetes.

Distribution protocols [recommended](#) by ACIP are [informed](#) in part by the National Academy of Medicine (NAM)'s [framework](#). The framework includes a [four-phased approach](#) to equitable COVID-19 vaccine allocation, with all groups within each phase having equal priority. The NAM phases 2 through 4 are as follows:

- **[Phase 2: K–12 teachers and school staff; child care workers; critical workers in high-risk settings](#)** (for example, the food supply system, public transit and other vital services); **[people of all ages with underlying health conditions that put them at moderately higher risk; people in homeless shelters or group homes](#)** (including those for people with disabilities or in recovery);

people in prisons, jails, detention centers and similar facilities that limit opportunities for physical distancing; and **all older adults** not included in earlier phases

- **Phase 3: Young adults, children and workers in industries important to the functioning of society and at moderately high risk of exposure.** This group includes personnel at universities, entertainment and goods-producing industries where protective measures can be implemented without difficulty.
- **Phase 4: Everyone residing in the United States.** Anyone who did not have access to the vaccine in prior phases falls into the last group.

Allocation of COVID-19 vaccines to jurisdictions is based on multiple factors, including critical populations, current local spread/prevalence of COVID-19, and vaccine production and availability. Allocations may shift based on supply, demand and risk.

Employer as closed point-of-dispensing (POD) setting. Certain employers' type of business might enable them to work with state or local public health authorities as closed PODs for COVID-19 vaccine administration. Local public health departments can use two types of PODs — open and closed — in a public health emergency:

- Open PODs are typically operated by local public health agencies and located at public sites like arenas, community centers or schools.
- Closed PODs are sites staffed and managed by organizations and agencies (both public and private) to dispense the vaccine only to their own populations.

The CDC's vaccine playbook for jurisdictions encourages states to consider developing closed PODs to administer COVID-19 vaccines. An employer with a threshold number of covered lives and the infrastructure to transport, store and administer COVID-19 vaccines might qualify as a closed POD. Any employer considering this route might want to review the closed POD fact sheet and associated roles and responsibilities before contacting the appropriate state or local public health agency. If a closed POD agreement is signed, when the supply is received by the state or locality, the employer picks up the vaccines and handles administering them to employees.

Requiring the vaccine

Some employers have been considering whether to make COVID-19 vaccines a mandatory condition for returning to the workplace. Before moving forward with such a mandate, employers should consult with employment law counsel and keep the following considerations in mind.

CDC and Equal Employment Opportunity Commission (EEOC) guidance. Guidance from these agencies provides insight into the appropriateness of an employer-imposed vaccine mandate. The

Americans with Disabilities Act (ADA) prohibits employers from asking employees or applicants about disabilities or requiring medical examinations, unless the inquiries or exams are job-related and consistent with business necessity (or part of a voluntary wellness program). Updated EEOC guidance says that the administration of the COVID-19 vaccine is not a “medical examination” subject to the ADA. However, the patient screening questions posed before administration of the vaccine are likely “disability-related inquiries” covered by the ADA.

If, as a condition returning to the workplace, employees must receive a COVID-19 vaccine through a vaccination program that the employer administers (directly or through a third-party contractor), the employer must show that the screening questions are “job-related and consistent with business necessity.” On the other hand, if the employer merely requires an employee to provide proof of vaccination from an unrelated third party (e.g., a pharmacy or a healthcare provider), the ADA doesn’t apply as long as the proof doesn’t include medical information and the employer doesn’t ask follow-up questions, such as asking why an employee did not get a vaccination.

When an employer’s vaccination mandate does trigger ADA protections, an employer can screen out an unvaccinated employee due to a disability only if the employee poses a “direct threat to the health or safety” that no reasonable accommodation could reduce or eliminate without causing undue hardship to the business. In related guidance, the EEOC reminds employers covered by the ADA and Title VII of the Civil Rights Act of 1964 that even during a pandemic, an employer must make reasonable accommodations for employees who object to the vaccine due to an ADA-protected disability or sincerely held religious belief.

The ADA and Title VII continue to apply during the coronavirus pandemic, but employers can still follow the CDC recommendations for workplaces and businesses. As COVID-19 vaccination gets underway and the pandemic evolves, employers should regularly check EEOC and CDC resources for updated guidance and FAQs.

State law and guidance. If COVID-19 cases continue to increase and stress the healthcare system after COVID-19 vaccines become readily available, guidance from state authorities could alter the undue hardship analysis under either the ADA or Title VII. An employer’s obligation to adhere to local requirements could bolster its case for a vaccine mandate.

Trust in the vaccine, healthcare industry and political leaders. The politicized and polarizing debate over COVID-19 preventive measures is likely to continue, with some questioning the vaccine’s efficacy and safety. Requiring vaccination as a condition for returning to the workplace could trigger a large number of accommodation requests, fueled by mistrust of political leaders and the healthcare industry. A Pew Research Center study in September found that only 51% of adults were willing to take the vaccine, with 77% percent distrusting its safety and effectiveness. An October poll from the COVID Collaborative found that 84% of African Americans and 80% of Latin Americans expressed concern that political

expediency could compromise a vaccine's safety and efficacy. Overall skepticism may be waning: A Kaiser Family Foundation [poll](#) released Dec. 15 found 71% of Americans definitely or probably would get the vaccine, though responses varied by race, political party and geographic location.

Carrot, rather than stick, may be preferred approach. Rather than imposing a vaccine mandate, some employers might consider voluntary programs or incentives to boost vaccination rates among employees. For the flu shot, the EEOC generally recommends that employers simply encourage rather than require employees to get the vaccine. With respect to an employer-sponsored voluntary COVID-19 vaccination program, the EEOC says that if the employee declines to answer the necessary disability-related screening questions, the employer can simply decline to administer the vaccine. Some employers might consider adding COVID-19 vaccination incentives to an existing voluntary wellness program that offers rewards for certain activities. While voluntary wellness programs have certain compliance obligations — and uncertainty around permissible incentives in a wellness program subject to the ADA — these programs may be less legally cumbersome than mandatory programs. A voluntary program with incentives could also work better with skeptical employees who otherwise might seek accommodations from a vaccine mandate.

Administrative issues may be insurmountable. Whether an employer chooses to mandate the vaccine or encourage it with incentives, administrative issues may discourage many employers from adopting either approach. Employers with the facilities and personnel to administer vaccines to staff will need to track and monitor which employees have received the first and subsequent doses of the vaccine and ensure medical data protections are in place. Employers will also need provide timely access to any required doses after the first shot.

Community encouragement may be the best approach. Even without a vaccine mandate or wellness incentives, employers can encourage employees to get vaccinated by regularly issuing carefully crafted, educational communications that provide reliable information — for example, content from public health announcements and websites. Employers can also lead by example by having senior managers and other “influencers” in the organization share their vaccination experiences. The campaign could be further buttressed by offering paid time off for employees to get the vaccine or paid sick leave to recover from any side effects.

Coverage beyond the public health emergency

As described earlier, during the HHS-declared public health emergency, nongrandfathered group health plans must cover COVID-19 vaccines without cost sharing, regardless of whether an in-network or an out-of-network provider administers the vaccine. Once the public health emergency ends, group health plans may want to consider whether to continue no-cost-sharing coverage for COVID-19 preventive services received from *out-of-network* providers.

The federal government has paid for the initial wave of COVID-19 vaccines, but plans may have to cover the expense once those doses are exhausted. Some employers have expressed concerns in a [letter](#) to HHS about potential price gouging for COVID-19 vaccines and treatments.

Plans may want to compare in-network vs. out-of-network vaccine costs for several months before deciding whether to continue coverage for all vaccine providers without cost sharing. Once the public health emergency expires, the vaccine may be available widely enough to limit no-cost-sharing coverage to in-network providers, without causing adverse impact for plan participants. Group health plan sponsors may need to adopt plan amendments and provide advance notice to participants if making coverage changes in the middle of a plan year.

State law exceeding federal requirements

Employers sponsoring insured nongrandfathered group health plans may want to keep an eye on state laws addressing COVID-19 vaccine coverage that may go beyond what the CARES Act and the interim final rule require. The Commonwealth Fund [reports](#) that at least 10 states have issued directives requiring or encouraging insurers to cover coronavirus vaccines without cost sharing. Employers with insured plans should watch for other state developments on vaccine coverage, particularly if the federal interim final rule requiring no-cost-sharing coverage of out-of-network COVID-19 preventive services expires, yet some states are still grappling with a public health crisis.

Employer next steps

This interim final rule may not be the last guidance issued on required coverage of COVID-19 preventive services. More COVID-19 vaccines are expected to gain approval shortly, so plans should prepare to provide coverage without cost sharing within 15 business days — or sooner if possible — of the ACIP or USPSTF recommendation. Here are some key steps for employers to consider.

- Review plan documents to determine if any amendments are needed.
- Consult with legal counsel before developing a vaccination policy for the workforce.
- If interested in becoming a closed POD site for vaccine administration site, reach out to state and local public health authorities.

Related resources

Non-Mercer resources

- [ACIP vaccine recommendations and guidelines](#) (ACIP)

- [What you should know about COVID-19 and the ADA, the Rehabilitation Act and other EEO laws](#) (EEOC, Dec. 16, 2020)
- [How CDC is making COVID-19 vaccine recommendations](#) (CDC, Dec. 13, 2020)
- [COVID-19 vaccine provider toolkit](#) (CMS, Dec. 3, 2020)
- [Interim final rule: Rapid coverage of COVID-19 preventive services and price transparency for COVID-19 diagnostic tests](#) (Federal Register, Nov. 6, 2020)
- [COVID-19 vaccine toolkit for health and drug plans](#) (CMS, Nov. 5, 2020)
- [Fact sheet: Fourth COVID-19 interim final rule with comment period \(IFC-4\)](#) (CMS, Oct. 28, 2020)
- [Press release: Trump administration acts to ensure coverage of life-saving COVID-19 vaccines & therapeutics](#) (Oct. 28, 2020)
- [Pub. L. No. 116-136, the CARES Act](#) (Congress, March 27, 2020)
- [Pub. L. No. 116-127, the FFCRA](#) (Congress, March 18, 2020)

Mercer Law & Policy resources

- [Plan coverage of COVID-19 testing: Issues remain after June guidance](#) (Sept. 15, 2020)
- [Employer health plans have to meet new COVID-19 coverage mandate](#) (April 21, 2020)
- [CARES Act boosts telehealth, makes other health, paid leave changes](#) (March 27, 2020)

Other Mercer resources

- [Navigating the coronavirus](#) (regularly updated)
- [Employers can mandate the covid-19 vaccine, but should they?](#) (Dec. 10, 2020)
- [COVID-19 relief for health plans: How long does it last?](#) (Dec. 3, 2020)
- [Getting ready for a COVID-19 vaccine](#) (Oct. 8, 2020)
- [Contact tracing at work, works — and it's not that complicated](#) (July 30, 2020)
- [Worksite employee COVID-19 testing covered by insurance? — Not so fast!](#) (July 16, 2020)

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